SEP 2 0 2001

A. 510(K) SUMMARY

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010981.

SUBMITTER: MEDOC Advanced Medical Systems
45 Ha'oren St.
Ramat Yishai 30095, Israel

CONTACT PERSON: Ann Quinlan-Smith, Alquest, Inc

DATE PREPARED: March 30, 2001

TRADE NAME: GSA Genito Sensory Analyzer

COMMON NAME: Thermal Sensitivity Tester
Vibration Threshold Measurement Device

CLASSIFICATION: 21 CFR Section 882
Unclassified, as are the predicate devices

PRODUCT CODE: LQW/LLN

PREDICATE DEVICE(S): MEDOC Advanced Medical System's TSA device, cleared via 510(k) K922052 on October 21, 1993, for use in evaluating the function/dysfunction of the small nerve fibers by measuring the sensory thresholds.

MEDOC Advanced Medical System's VSA device, cleared via 510(k) K970180 on April 25, 1997, for use in the quantitative assessment of large nerve fiber dysfunction using the sensory threshold for vibration

DEVICE DESCRIPTION: The GSA Genito Sensory Analyzer consists of the standard Thermal Sensory Analyzer (TSA) and Vibratory Sensory Analyzer (VSA) componentry, together with special thermal and vibratory probes and holders adapted for examining the anatomical regions of the vagina, clitoris and anus for assessment of dysfunction of the pelvic floor nerves.

INTENDED USE:

The GSA Genito Sensory Analyser is intended for the measurement of thermal and vibratory thresholds or sensibility in clinical situations where various neuropathies or nerve damage may exist, particularly in nerves of the pelvic floor.

SUBSTANTIAL EQUIVALENCE:

The predicate devices, the MEDOC Advanced Medical Systems Thermal Sensory Analyzer (TSA) and Vibratory Sensory Analyzer (VSA), are identical in principles of operation, in materials and circuitry and in general intended use. The TSA and VSA contain identical hardware and firmware as that in the GSA. The function of the GSA is identical to that of the TSA and VSA, in that it is intended to evaluate sensory nerve fibers.

The only differences in the Genito Sensory Analyzer (GSA) relate to the ergonomics of the thermal and vibratory probes, minor modifications of the system software, and the specific subset of the general indication for which this product will be labeled.

CONCLUSION:

Testing and safety analyses have demonstrated that the modified Medoc GSA device performs according to its required specifications and in a manner equivalent to the predicate device. The product is designed and manufactured in accordance with required regulations and in a controlled, consistent manner.

The modified indications for use constitute a more specific subset of the general indication for the predicate devices and clinical experience shows that quantitative sensory testing is useful for diagnosing and monitoring treatment of nerve dysfunction.

Therefore, the Genito Sensory Analyser is substantially equivalent to the predicate products: the Thermal Sensory Analyser (TSA) and the Vibratory Sensory Analyser (VSA).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Ms. Ann Quinlan-Smith
Principal Consultant, Alquest, Inc.
Consultant to MEDLOC Advanced Medical Systems
11660 Wayzata Boulevard
Minnetonka, Minnesota 55305-2010

Re: K010981
Trade/Device Name: GSA Genito Sensory Analyzer
Regulation Number:
Regulation Name:
Regulatory Class: No Classification Number
Product Code: LLN
Dated: July 17, 2001
Received: July 18, 2001

Dear Ms. Quinlan-Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, M.D.

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE PAGE

510(k) Number (if known): Not yet assigned. K010981

Device Name:

MEDOC Advanced Medical Systems GSA Genito Sensory Analyser

Indications For Use:

The GSA Genito Sensory Analyser is intended for the measurement of thermal and vibratory thresholds or sensibility in clinical situations where various neuropathies or nerve damage may exist, particularly in nerves of the pelvic floor.

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010981